K020886

NOV 1 2002

510(k) SUMMARY

Puritan Bennett
GoodKnight 420 SERIES

1.0 - Submitter Information

Tyco Healthcare Nancy
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France

Submitter's Name : Moustafa Anki
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Preparation Date : March 2002

2.0 - Device Name

Proprietary Name : Puritan Bennett, GoodKnight 420G
: Puritan Bennett, GoodKnight 420S
Common Name : CPAP Machine
Device Classification Name : Noncontinuous Ventilator (73 BZD), per 21 CFR 868.5905

3.0 - Predicate Device Equivalence

We are claiming substantial equivalence to the Puritan Bennett GoodKnight 418G CPAP device, cleared for commercial distribution as per K991150.

4.0 - Device Description

The GoodKnight 420 Series Devices consist of the following elements:

- GoodKnight 420G (GK420G) C-PAP Machine;
- GoodKnight 420S (GK420S) C-PAP Machine.

The GoodKnight 420 Series Devices are designed to deliver Continuous Positive Airway Pressure between 4 and 20 cmH_2O.

The GoodKnight 420 Series Devices can be powered either by AC mains (100 VAC to 240 VAC nominal) or by an external 12 VDC battery. The blower motor nominal voltage is 13 VDC. The GoodKnight 420 Series power supply is double-insulated so that grounding is not required.

The GoodKnight 420 Series Devices are set up for use by the homecare dealer using the Clinician Manual provided. The devices are operated according to the instructions contained in the Patient Manual.

The GoodKnight 420 Series devices rely on a microprocessor for setting and viewing various control parameters and turning features on and off. The microprocessor is also required for the treatment of various signals from the devices including signals relating to patient cycle detection.

The GoodKnight 420 Series devices operate only in either Constant mode. In Constant mode, the main function of the device is to deliver constant positive airway pressure to the patient at a fixed level prescribed by the practitioner and between 4 and 20 cmH_2O.

Pressure delivery for the GoodKnight 420 Series Devices is regulated by a pressure sensor which monitors both ambient and output pressure and provides feedback to the control system.

The GoodKnight 420 Series Devices use the same pass over humidifier and masks as those approved for use with the GoodKnight 418G. The GoodKnight 420 Series Device tubing is equivalent to that of the GoodKnight 418G with the exception of an additional internal tube used for measuring the pressure at the patient's mask on the 420S model.

The GoodKnight Control clinical remote is also available for use with the GoodKnight 420S Device. The remote is used by the practitioner to configure the devices from a distance via a serial link.

The GoodKnight 420S Device can also be connected to a computer via an RS232 serial port. The device can be configured from the computer using the Silverlining™2 software which is required for downloading and displaying compliance data stored in the device memory.

The GoodKnight 420 Series Devices are not for use in life-supporting or life-sustaining situations. The devices and/or their accessories are not intended for sterile use.

The GoodKnight 420 Series Devices and the air filter are for multiple use. Accessories such as the patient circuit and nasal masks are for single patient use.

The GoodKnight 420 Series Devices are for use by prescription only and display the appropriate labeling.

The GoodKnight 420 Series Devices are for use in a hospital and homecare environment.

The GoodKnight 420 Series Devices do not contain any drugs or biological products as components. However, the devices can be used to provide the patient with supplemental oxygen.

The GoodKnight 420 Series Devices are not part of a kit.

The GoodKnight 420 Series Devices use software to set the various device parameters such as the prescription pressure and the ramp starting pressure.

The GoodKnight 420 Series Devices are electrically operated.

The GoodKnight 420 Series Devices comply with certain voluntary standards, specifically the draft ARDB Reviewer Guidance for Premarket Notification Submissions (Nov 1993) and IEC 60601-1.

5.0 - Intended Use

The intended use of the GoodKnight 420 Series Devices is to provide Continuous Positive Airway Pressure (C-PAP) between 4 and 20 cmH_2O to spontaneously breathing patients over 30 Kg for the treatment of Obstructive Sleep Apnea in a hospital and homecare environment.

6.0 - Comparison of Technological Characteristics

The GoodKnight 420 devices deliver pressure from 4 to 20 cmH_2O. The prediacte device delivers pressure from 4 to 18 cmH_2O.

The global architecture of the GoodKnight 418G and the GoodKnight 420 Series Devices is similar.

The voltage range for the GoodKnight 420 Series Devices is 100 to 240 VAC nominal or 13 VDC. The voltage range for the predicate device is 115 VAC or 23 VAC or 13 VDC. The GoodKnight 418G and the GoodKnight 420 Series Devices are all double-insulated.

As with the GoodKnight 418G, the GoodKnight 420 Series Devices use a microprocessor to set the various controls. In common with the GoodKnight 418G, the GoodKnight 420 Series Devices have a ramp function which, when activated, progressively attains the set reference pressure within a designated time between 0 to 30 minutes.

The user interfaces of the GoodKnight 418G and the GoodKnight 420 Series Devices are similar. All three devices use an LCD screen with a four button keypad (one of which is hidden) to access and view various device settings. Available settings on the GoodKnight 420 Series Devices depend upon the device itself and the mode of operation.

The Altitude Compensation feature of the GoodKnight 418G is not a characteristic of the GoodKnight 420 Series Devices. A pressure sensor, common to both GoodKnight 420G and 420S devices, monitors the output and ambient pressure, providing the patient with the right pressure whatever the altitude.

Unlike the GoodKnight 418G where pressure delivery is regulated by motor speed, the GoodKnight 420 Series Devices regulate pressure delivery according to the pressure sensor feedback signal.

The GoodKnight 418G and the GoodKnight 420 Series Devices have the common feature of compliance and hour meters. However, the GoodKnight 420S also has a data storage facility for registering information concerning the patient's events detected for up to 100 sessions. The data memory can be accessed by connecting a PC to the RS232 type interface at the back of the device and through the use of the Silverlining ™2 software.

7.0 - Summary of Performance Testing

1. Functional testing was performed to confirm that the GoodKnight 420 Series Devices are capable of meeting their stated performance specifications. The series passed all tests.
2. Testing was performed to confirm that the GoodKnight 420 Series Devices comply with the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the Division of Cardiovascular, Respiratory, and Neurological Devices. The devices passed all tests.
3. All software was tested in accordance with the May 29, 1998 "Guidance for the Content of Premarket submissions for Software Contained in Medical Devices" published by the Office of Device Evaluation. The devices passed all tests.

8.0 - Conclusions

We conclude that the GoodKnight 420 Series Devices meet the stated performance specifications and criteria outlined in the Reviewers Guidance publications referenced above. We conclude that the devices and their accessories will operate safely in their intended environment and will be effective in fulfilling their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2002

Mr. Moustafa Anki
Regulatory Affairs Manager
Tyco Healthcare Nancy
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F-54601 Villers-lès-Nancy cedex
FRANCE

Re: K020886
Trade/Device Name: Puritan Bennett, GoodKnight 420 Series
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: August 1, 2002
Received: August 5, 2002

Dear Mr. Anki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

K020886

Device Name:

Puritan Bennett, *GoodKnight 420 Series*

Intended Use:

The Puritan Bennett *GoodKnight 420 Series* is intended for use in treating obstructive sleep apnea (OSA) in spontaneously breathing patients weighing over 30 kg within a homecare and hospital environment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

510(k) number: K020886

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K020886